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<p>(51) International Patent Classification ⁷ : A61M 16/04, A61F 5/56</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/15283 (43) International Publication Date: 23 March 2000 (23.03.00)</p>
<p>(21) International Application Number: PCT/US99/20495 (22) International Filing Date: 9 September 1999 (09.09.99) (30) Priority Data: 60/100,623 16 September 1998 (16.09.98) US (71)(72) Applicant and Inventor: THORNTON, W., Keith [US/US]; 5524 Edlen, Dallas, TX 75220 (US). (74) Agent: KENNERLY, Christopher, W.; Baker & Botts, L.L.P., 2001 Ross Avenue, Dallas, TX 75201-2980 (US).</p>		<p>(81) Designated States: AU, CA, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: DEVICE AND METHOD FOR IMPROVING BREATHING</p> <p>(57) Abstract</p> <p>A device (10) for improving the breathing of a user includes an upper arch (12) adapted to receive at least some of the user's upper teeth, a lower arch (14) adapted to receive at least some of the user's lower teeth, and an engager (104) that engages the lower arch (14). An adjustor (100) adjusts the engager (104) forwardly relative to the upper arch (12). A slotted plate (114) couples the adjustor (100) to the upper arch (12) and adjustably positions the lower arch (14) vertically relative to the upper arch (12).</p>		

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DEVICE AND METHOD FOR IMPROVING BREATHING

TECHNICAL FIELD OF THE INVENTION

This invention relates generally to medical and dental appliances, and more particularly to a device and method
5 for improving breathing and method for fitting same.

BACKGROUND OF THE INVENTION

Many people experience breathing problems, which may result in difficulty sleeping, in snoring, or in other more
10 serious conditions such as obstructive sleep apnea. One treatment for such breathing disorders involves the use of devices inserted into a user's mouth for extending the user's lower jaw forward, possibly in conjunction with a face mask for supplying air to the user. These devices
15 open the breathing passageway more fully to allow easier breathing through the nose and mouth.

As technology continues to advance and users continue to demand increased comfort and performance, improving the breathing of users has become increasingly important.
20 Previous devices for improving breathing have included upper and lower arches that are connected together outside a user's mouth and then inserted into the user's mouth as an integrated unit to position the user's lower jaw forward. Although these devices may treat some breathing
25 problems, these devices do not sufficiently treat more serious conditions such as obstructive sleep apnea, while

also allowing the user or a clinical professional to adjust the position of the user's lower jaw after the arches have been inserted into the user's mouth. Furthermore, these devices do not allow the forward and vertical positions of the lower jaw to be adjusted independently and relatively easily. Moreover, these devices are often unwieldy and uncomfortable for the user with respect to insertion into the user's mouth and subsequent use after insertion into the user's mouth. As a result of these and other deficiencies, such devices and methods for improving breathing are inadequate for the needs of many users.

SUMMARY OF THE INVENTION

In accordance with the present invention, disadvantages and problems associated with devices for improving breathing and methods for fitting such devices have been substantially reduced or eliminated.

According to one embodiment of the present invention, a device for improving the breathing of a user includes an upper arch adapted to receive at least some of the user's upper teeth, a lower arch adapted to receive at least some of the user's lower teeth, and an engager that engages the lower arch. An adjustor adjusts the engager forwardly relative to the upper arch. A slotted plate couples the adjustor to the upper arch and adjustably positions the lower arch vertically relative to the upper arch.

Important technical advantages of the present invention include providing a device for improving breathing that a user or clinical professional may adjust relatively easily to more optimally fit the user so as to provide increased comfort and performance. The present invention allows the position of the lower arch to be adjusted both forwardly and vertically relative to the upper arch, and allows the forward and vertical positions of the lower arch to be adjusted independently, according

to particular needs. Furthermore, the present invention allows the forward and vertical positions of the lower arch to be adjusted while the device is inserted into the user's mouth. As a result, a user or clinical professional may
5 adjust the relative positions of the lower arch and upper arch relatively easily to provide increased fit, comfort, and performance in treating breathing disorders such as obstructive sleep apnea. Other important technical advantages are apparent to one skilled in the art from the
10 following figures, description, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and the advantages thereof, reference is now made
15 to the following description taken in conjunction with the accompanying drawings, wherein like reference numerals represent like parts, in which:

FIGURE 1 illustrates a device for improving breathing according to the present invention;

20 FIGURE 2 illustrates a device for improving breathing according to the present invention;

FIGURE 3 illustrates an upper arch according to the present invention;

25 FIGURE 4 illustrates indices and a zero set according to the present invention; and

FIGURE 5 illustrates a slotted plate having a slot for a hook according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

30 FIGURES 1 and 2 illustrate a device 10 having an upper arch 12 adapted to receive one or more of a user's upper teeth. Device 10 also includes a lower arch 14 adapted to receive one or more of a user's lower teeth. Slotted plate 114 couples adjustor 100 to upper arch 12. Adjustor 100
35 may be coupled to slotted plate 14 using screws 20 or any

other suitable technique. In one embodiment, slotted plate 114 is coupled to upper arch 12 using one or more screws 16 inserted through corresponding slots 18 in slotted plate 114 and into upper arch 12. Slotted plate 114 may be
5 formed from stainless steel or any other suitable material. When screws 16 are sufficiently loosened, slotted plate 114 may be adjusted vertically to adjust the vertical position of adjustor 100 relative to upper arch 12. As discussed more fully below, adjustor 100 engages lower arch 14 such
10 that forward or vertical adjustment of adjustor 100 results in forward vertical adjustment, respectively, of lower arch 14 to improve the user's breathing.

Adjustor 100 includes a cylindrical or other suitable channel 110 that extends from the front of slotted plate
15 114 forward through adjustor 100 and into a rotating portion 102 of adjustor 100. A cylindrical coupler 112 includes a shaft disposed within channel 110 and an internally threaded head 108 that may rotate within adjustor 100 while engaged with threads on a shaft 106 of
20 an engager 104. Although engager 104 is shown as being a hook, the present invention contemplates other suitable techniques for engaging lower arch 14, as discussed below. Cylindrical coupler 112 is fixedly coupled to rotating portion 102 of adjustor 100, such that when rotating
25 portion 102 is rotated by hand or otherwise, cylindrical coupler 112 and head 108 of cylindrical coupler 112 are likewise rotated within channel 110. Although shaft 106 and cylindrical coupler 112 are shown as being accessible from the front of rotating portion 102 through a portion of
30 channel 110, the present invention contemplates rotating portion 102 covering or otherwise completely isolating the forward portions of shaft 106 and cylindrical coupler 112, rotating portion 102 being integral to cylindrical coupler 112, or any other suitable configuration. Although
35 rotating portion 102 and cylindrical coupler 112 may be

formed from any suitable material, in one embodiment cylindrical coupler 112 is formed from stainless steel or another relatively inert metal, and rotating portion 102 is formed from a suitable thermoplastic material that forms upper arch 12.

In operation, arches 12 and 14 are inserted into the user's mouth, either separately or together, and engager 104 removably engages a clasp 34 of lower arch 14, which extends between opposite sides of lower arch 14. Clasp 34 may be any suitable rod or similar member that extends between opposite sides of lower arch. Clasp 34 may be substantially circular in cross section or may have any other suitable configuration. Although clasp 34 is shown as substantially linear, the present invention contemplates any clasp 34 suitable to be removably engaged by engager 104 so as to allow lower arch 14 to be adjusted forwardly and vertically relative to upper arch 12 in the manners discussed above. When engager 104 is engaged with clasp 34, lower arch 14 is allowed to move laterally relative to upper arch 12, providing increased comfort to the user and improved treatment of the user's breathing disorder.

When rotating portion 102 of adjustor 100 is rotated in an appropriate direction, internal threads of head 108 of cylindrical coupler 112, which are engaged with threads of shaft 106 of engager 104, rotate to adjust engager 104 forwardly relative to upper arch 12. This adjusts lower arch 14 forwardly relative to upper arch 12 and extends the user's lower jaw forwardly relative to upper arch 12 from its natural position to reduce or eliminate snoring, obstructive sleep apnea, or other breathing disorders. Although the present invention is described in terms of adjusting lower arch 14 and thus the user's lower jaw forwardly, device 10 also operates to adjust lower arch 14 and the user's jaw rearwardly relative to upper arch 12, according to particular needs.

As discussed above, slotted plate 114 may be adjusted vertically to adjust the vertical position of adjustor 100 and, by virtue of the engagement of lower arch 14, the vertical position of lower arch 14 relative to upper arch 12. Vertical adjustment of lower arch 14 may be upward or downward according to particular needs. In one embodiment, the forward and vertical adjustability of lower arch 14 allows the user's lower jaw to be extended forward to a fixed forward position and adjusted vertically to a fixed vertical position. As a result of the combined and independent adjustment of the forward and vertical positions of lower arch 14, the device of the present invention is able to provide increased fit, comfort, and performance.

FIGURE 3 illustrates upper arch 12 of device 10. As shown in FIGURE 3, in which upper arch 12 is shown from below, a connector 120 may be removably coupled to adjustor 100 of upper arch 12 to allow upper arch 12 to be removably coupled to a face mask. In one embodiment, at least a portion of adjustor 100, for example, some or all of rotating portion 102, is pressure fitted into a cavity 122 of connector 120. Shaft 124 of connector 120 may then be coupled to the face mask using an appropriate connecting apparatus.

In one embodiment, shaft 106 of engager 104 is substantially flattened, as discussed more fully below with reference to FIGURE 5. In this case, only the rounded sides of shaft 106 are threaded and engage internal threads of head 108 of cylindrical coupler 112. As shown in exploded FIGURE 4, engager 104 includes indices 126 that cooperate with zero set 128 to indicate the extent of forward or rearward adjustment of engager 104 relative to upper arch 12, which in turn indicates the extent of forward adjustment of lower arch 14 and therefore the user's lower jaw. Similar indices and zero set may be used

in connection with slotted plate 114 to indicate the extent of vertical adjustment of lower arch 14 and therefore the user's lower jaw. Although indices 126 and zero set 128 are discussed, the present invention contemplates any
5 suitable technique for indicating the extent to which the user's lower jaw is adjusted.

FIGURE 5 illustrates slotted plate 114, shown from the rear, that adjustably couples adjustor 100 to upper arch 12. In addition to slots 18, slotted plate 114 includes a
10 horizontal slot 116 through which shaft 106 of engager 104 extends through internally threaded head 108 of cylindrical coupler 112 and into the hollow interior of cylindrical coupler 112. In one embodiment, as discussed above, shaft 106 of engager 104 is substantially flattened, such that
15 slot 116 limits or prevents rotation of shaft 106 when rotating portion 102 of adjustor 100 is rotated to rotate internally threaded head 108 of cylindrical coupler 112. As a result, engager 104 is adjusted forwardly relative to upper arch 12 in response to rotation of internally
20 threaded head 108, for example, in the direction of arrow 118.

Although the present invention has been described above in connection with several embodiments, it should be understood that a plethora of changes, substitutions, variations, alterations, transformations, and modifications
25 may be suggested to one skilled in the art, and it is intended that the present invention encompass such changes, substitutions, variations, alterations, transformations, and modifications as fall within the spirit and scope of
30 the appended claims.

WHAT IS CLAIMED IS:

1. A device for improving the breathing of a user, comprising:

an upper arch adapted to receive at least some of the
5 user's upper teeth;

a lower arch adapted to receive at least some of the
user's lower teeth;

an engager operable to engage the lower arch;

an adjustor operable to adjust the engager forwardly
10 relative to the upper arch; and

a slotted plate coupling the adjustor to the upper
arch and operable to adjustably position the lower arch
vertically relative to the upper arch.

15 2. The device of Claim 1, wherein the slotted plate
comprises a vertical slot operable to receive a fastener.

3. The device of Claim 1, wherein at least a portion
of the adjustor is operable to be rotated to adjust the
20 engager forwardly.

4. The device of Claim 1, wherein the upper arch
further comprises an engager slot through which at least a
portion of the engager passes, the engager slot operable to
25 limit the rotation of the engager.

5. The device of Claim 1, wherein the adjustor
comprises an internally threaded portion operable to engage
threads of the engager.

30

6. The device of Claim 1, wherein the lower arch
comprises a clasp that extends laterally between opposite
sides of the lower arch, the engager engaging the clasp to
engage the lower arch.

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7. The device of Claim 1, wherein the vertical position of the lower arch is adjustable after the upper arch and the lower arch are inserted into the user's mouth.

5 . 8. The device of Claim 1, wherein the device allows lateral movement of the lower arch after the device has been inserted into the user's mouth.

9. A method for improving the breathing of a user, comprising:

inserting an upper arch into the user's mouth, the upper arch adapted to receive at least some of the user's upper teeth;

inserting a lower arch into the user's mouth, the lower arch adapted to receive at least some of the user's lower teeth;

engaging the lower arch using an engager;

adjusting the engager forwardly relative to the upper arch using an adjustor; and

adjusting a slotted plate coupling the adjustor to the upper arch to adjustably position the lower arch vertically relative to the upper arch.

10. The method of Claim 9, wherein adjusting the slotted plate comprises:

sliding the slotted plate about a fastener passing through the slotted plate; and

securing the fastener to fix the vertical position of the slotted plate.

11. The method of Claim 9, wherein adjusting the engager forwardly comprises rotating at least a portion of the adjustor.

12. The method of Claim 9, wherein the slotted plate comprises an engager slot through which at least a portion of the engager passes, the engager slot limiting the rotation of the engager.

13. The method of Claim 9, further comprising engaging threads of the engager with an internally threaded portion of the adjustor.

14. The method of Claim 9, wherein engaging the lower arch comprises engaging a clasp extending laterally between opposite sides of the lower arch.

5 15. The method of Claim 9, further comprising allowing lateral movement of the lower arch after the device has been inserted into the user's mouth.

16. A method for fitting a device for improving the breathing of a user, comprising:

inserting an upper arch into the user's mouth, the upper arch adapted to receive at least some of the user's upper teeth;

inserting a lower arch into the user's mouth, the lower arch adapted to receive at least some of the user's lower teeth;

engaging the lower arch using an engager after the upper arch and the lower arch have been inserted into the user's mouth;

adjusting the engager forwardly relative to the upper arch using an adjustor after the upper arch and the lower arch have been inserted into the user's mouth; and

adjusting a slotted plate coupling the adjustor to the upper arch after the upper arch and the lower arch have been inserted into the user's mouth to adjustably position the lower arch vertically relative to the upper arch to fit the device.

17. The method of Claim 16, wherein adjusting the slotted plate comprises:

sliding the slotted plate about a fastener passing through the slotted plate; and

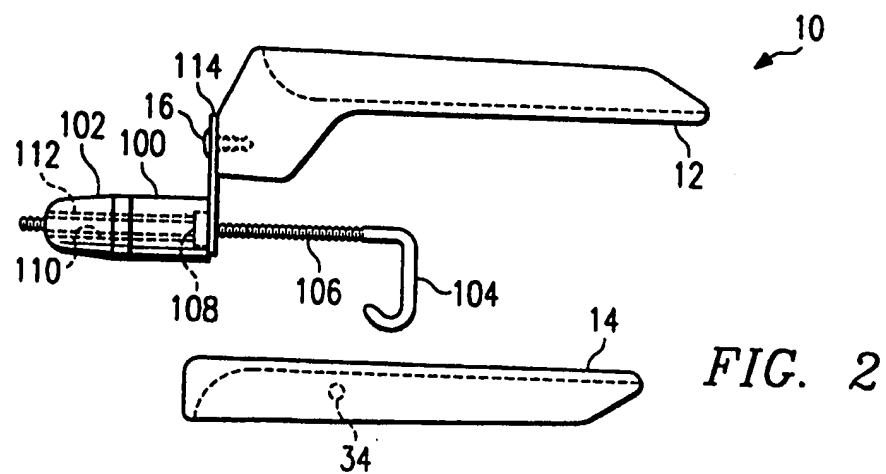
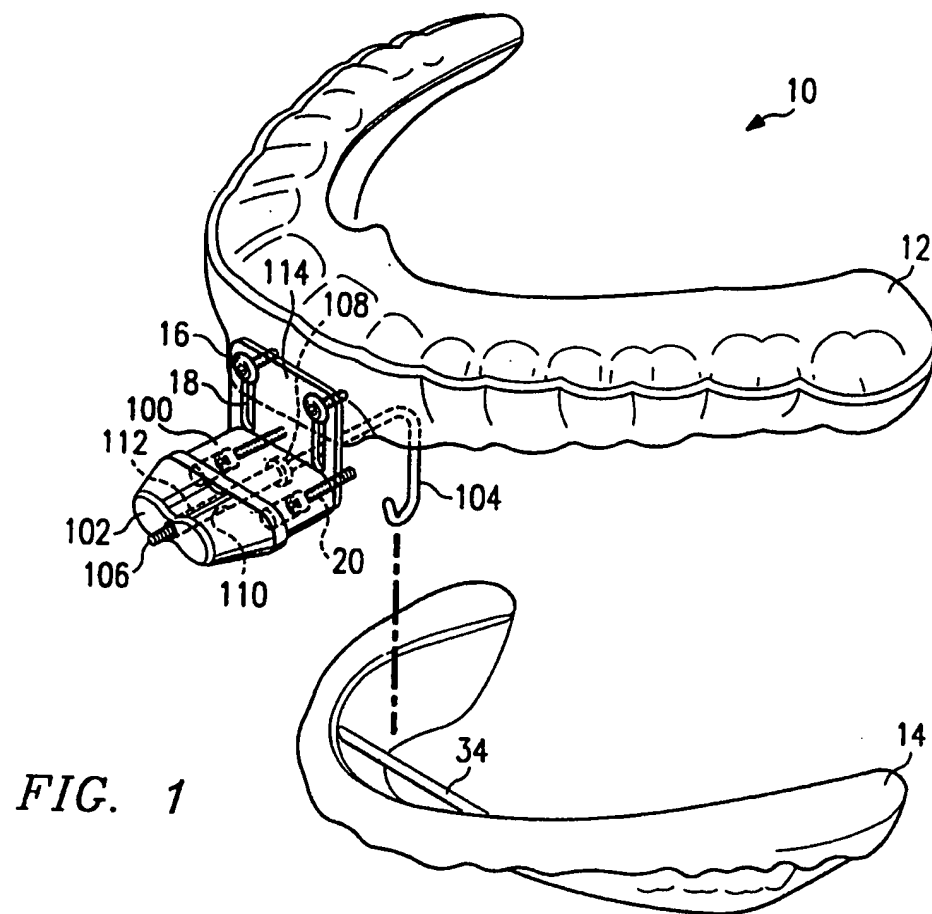
securing the fastener to fix the vertical position of the slotted plate.

18. The method of Claim 16, wherein adjusting the engager forwardly comprises rotating at least a portion of the adjustor.

19. The method of Claim 16, wherein the slotted plate comprises an engager slot through which at least a portion of the engager passes, the engager slot limiting the rotation of the engager.

20. The method of Claim 16, further comprising engaging threads of the engager with an internally threaded portion of the adjustor.

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2/2

FIG. 3

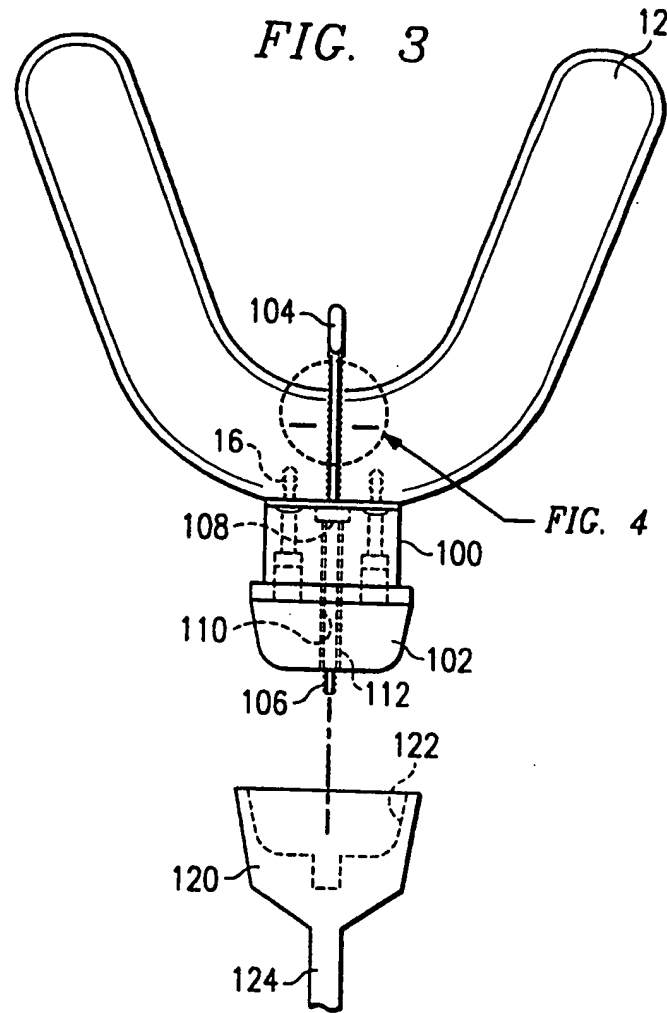


FIG. 4

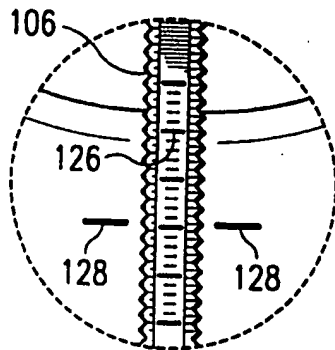
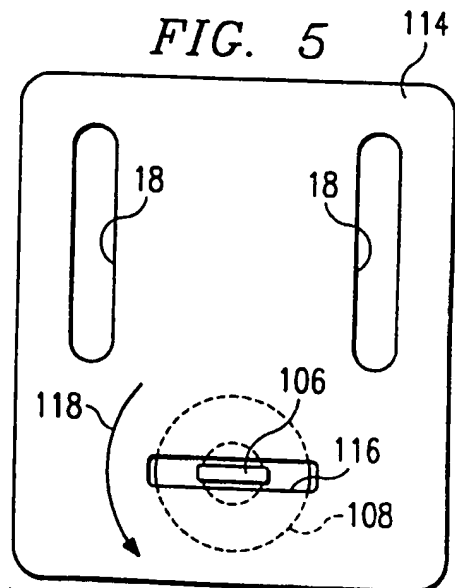


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/20495

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/04 A61F5/56

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61F A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 23673 A (HALSTROM LEONARD WAYNE) 27 October 1994 (1994-10-27)	1
Y	page 9, line 4 -page 10, line 20; figures 3-8	3,6-8
Y	WO 97 25010 A (THORNTON W KEITH) 17 July 1997 (1997-07-17)	3,6-8
	page 10, line 22 -page 12, line 18; figures 2A-2C	
A	WO 95 08969 A (THORNTON W KEITH) 6 April 1995 (1995-04-06)	1
	page 9, line 1 -page 11, line 14; figures 2A-2D	
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search

21 December 1999

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11/01/2000

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 409 017 A (LOWE ALAN A) 25 April 1995 (1995-04-25) column 2, line 54 -column 5, line 17; figures	1
A	WO 95 33418 A (THORNTON W KEITH) 14 December 1995 (1995-12-14)	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 20495

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body
by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l Application No

PCT/US 99/20495

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